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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,991	03/28/2001	Maurice Zauderer	1821.0050004	9763

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EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/818,991	Applicant(s) ZAUDERER ET AL.	
	Examiner Padmashri Ponnaluri	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-138* is/are pending in the application.

4a) Of the above claim(s) *11-21,31-42,63 and 89-137* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,22-30,43-62,64-88 and 138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to the Election/Restrictions

1. Applicant's election without traverse of WR as species vaccinia virus vector, in Paper No. 10, filed on 9/11/03 is acknowledged.

2. Applicant's election without traverse of group I, claims 1-10, 22-88; and the following species election of a) expression of a suicide gene product, b) osteoclast progenitor stem cell, c) tissue culture plastic, d) tissue culture plate, e) cDNA library, f) target polynucleotide that directly regulates osteoclast differentiation, g) a suicide gene that encodes Diphtheria toxin A subunit, h) tissue restricted promoter, I) osteoclast progenitor cell, j) poxvirus vector, k) vaccinia virus vector, l) vaccinia virus p7.5 promoter, m) vaccinia virus linear genome, n) fowlpox virus as helper virus, o) vaccinia virus p 7.5 transfer plasmid promoter, in Paper No. 8, filed on 5/27/03 is acknowledged.

3. Applicant's election **without traverse of group I, claims 1-10, 22-88**, in Paper No. 8 is acknowledged. However applicant's stated claims 89-109, which were originally grouped as IV, depend ultimately from claim 1, and are actually directed to a method of selecting target polynucleotide should be examined along the elected group I. The traversal is on the ground(s) that group IV claims are dependent on elected group I, and are drawn to a method of selecting a target polynucleotide. This is not found persuasive because group IV invention is drawn to a method of constructing a library of insert polynucleotides, which is different from the elected group I method of selecting a target polynucleotide by introducing into a population of host cells a library of insert polynucleotides. Inventions of group I (process of use of the product, i.e., insert library) and Group IV (process of making the product, i.e., insert library) are related as method

of making the product and process of use of the product. In the instant case the method of making a product (insert library) is not required for practicing the process of use of the product, and any other product, insert library , need not to be prepared by the instant group IV method can be used in the method of group I.

The requirement is still deemed proper and is therefore made FINAL.

Status of claims

4. Claims 11-21, 89-137 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

5. Claims 31-42, 63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species election, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

6. The preliminary amendment A, filed on 9/11/03 has been considered and entered into the application. New claim 138 has been added by the amendment A, filed on 9/11/03. Claims 1-138 are currently pending in this application.

7. Claims 1-10, 22-30, 43-62, 64-88 and 138 are currently being examined in this application.

Oath/Declaration

8. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Applicants in the specification indicated priority to several provisional applications. However, the oath, declaration does not acknowledge the priority to provisional applications. A new oath, declaration or application data sheet is required in the body of which the present application and priority applications, should be identified by application number and filing date.

Specification

9. The disclosure is objected to because of the following informalities: in the specification page 43, paragraph 261 and page 45, paragraph 289, 291, SEQ ID Nos are missing.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-10, 22-30, 43, 59-62, 64-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

The instant claim briefly recites a method of selecting a target polynucleotide comprising, a) introducing into a population of host cells a library of insert polynucleotides, and the expression of target polynucleotide in the host cell promotes cell death, b) culturing the host cells and c) collecting the insert polynucleotides from host cells.

The instant specification discloses the use of linear DNA virus vector such as vaccinia virus vector, and the cell death is the result of expression of a suicide gene product by the host cell. And further the specification discloses the use of host cells which contain a death domain receptor expressed on the surface of host cells. The specification discloses that the suicide gene product is diphtheria toxin A subunit. The specification has not disclosed the use of any type of host cells in the method of screening for a target polypeptide whose expression promotes cell death. The specification description is directed to specific host cells (which contain a cell death domain receptor) or RAW cells, and the use of Vaccinia virus vectors (especially vaccinia WR vectors) which clearly do not provide an adequate representation regarding the open ended claimed method for selecting a target polynucleotide of the instant claims.

> With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to DNA compounds, this holding would be deemed to be applicable to the method of screening; which requires a representative sample of showing of sufficient identifying characteristics of the products used to demonstrate possession of the claimed generic(s) and to demonstrate possession of products identified using the claimed method. In the present instance, the claimed invention contains no identifying characteristics regarding the identified polynucleotide or the host cells or the library of insert polynucleotides used. Additionally, the narrow scope of examples directed to use of specific host cells (host cells contain cell death domain receptor) and specific vaccinia virus vectors are clearly not representative of the scope of the presently claimed method.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 69-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claims 69-70 recite the limitation "the naturally occurring genome" . There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 1-10, 22-30, 43, 60, 62, 64-71, 76-79 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,712,115 (HAWKINS et al).

The instant claim briefly recites a method of selecting a target polynucleotide comprising, a) introducing into a population of host cells a library of insert polynucleotides, and the expression of target polynucleotide in the host cell promotes cell death, b) culturing the host cells and c) collecting the insert polynucleotides from host cells.

Hawkins et al disclose human cell death associated protein (CDAP), which was isolated from rheumatoid synovium library. The reference discloses genetically engineered expression vectors (refers to the library of insert polynucleotides of the instant claims) and host cells comprising CDAP. The reference discloses that nucleotide sequence encoding CDAP is inserted into an appropriate expression vector, which contain necessary elements for transcription and translation of inserted coding sequence. The reference discloses that in mammalian host cells, a number of viral based expression systems may be utilized, the reference especially teaches the use of adenovirus vectors (i.e., see column 11). The reference discloses that host cells transformed with a CDAP nucleotide sequence may be cultured under conditions suitable for the

expression and recovery of the encoded protein from the cell culture (refers to instant claims 27-30). The protein produced by a recombinant cell may be secreted or contained intracellularly depending on the sequence and/or vector used (i.e., see column 13). The reference discloses that the host cells which contain the coding sequence for CDAP and express CDAP may be identified by a variety of procedures known to those of skill in the art (i.e., see column 12). The reference discloses that the CDAP can be assayed in BHK cells seeded on a microscopic cover slip (refers to the instant claims 7-9, 26) and transiently transfected with plasmid engineered to give rich expression, and the nuclei which express CDAP noticed to be apoptotic (i.e., see column 12) (refers to the instant claim method step c), and in column 13 the reference discloses the methods for purification of CDAP from host cells. Thus, the reference clearly anticipates the claimed invention.

17. Claims 1-10, 22-30, 43-62, 64-88 and 138 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0133917 A1 (ZAUDERER).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant claim briefly recites a method of selecting a target polynucleotide comprising, a) introducing into a population of host cells a library of insert polynucleotides, and the expression of target polynucleotide in the host cell promotes cell death, b) culturing the host cells and c) collecting the insert polynucleotides from host cells.

Zauderer discloses novel methods for the identification of antigens recognized by CTLs and specific for human tumors, cancers and infected cells. The reference discloses engineering of recombinant viruses as expression vectors for tumor, cancer or infected cell-specific antigens. The reference discloses that the tumor specific CTLs generated as described can be used to screen expression libraries prepared from target tumor cells (refers to the instant library of target insert polynucleotides) to identify clones encoding the target epitope(i.e., see paragraph 54 and 56 in page 6). The reference discloses the DNA library is constructed in vaccinia virus vectors, preferably trimolecular recombination method employing modified vaccinia virus vectors (i.e., see paragraph 57 in page 7). The reference discloses that the method is used to select for those cells infected with the recombinant virus that express the target epitopes of the specific cytotoxic T cells. An adherent monolayer of cells (refers to the host cells on solid support of the instant claims) is infected with recombinant viral vector library, e.g., vaccinia recombinant viral library as m.o.i. less than or equal to 1 (refers to instant claim 61) (i.e., see page 7, paragraph 59). The reference discloses that the some of the cells infected with recombinant particle leads to expression of the target epitope and undergo a lytic event. The cells which undergo the lytic event or released from the monolayer and can be harvested in the floating cell population. The above described protocol is repeated for preferably five or more cycles to increase the level of

enrichment obtained by this process (refers to the instant claim 3) (i.e., see page 7, paragraph 60). The reference clearly anticipates the claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884. The examiner is on Flex Schedule and can normally be reached from Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
01 December 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER